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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,293	03/26/2004	Andy H. Levine	2814.2008-001	8260

21005 7590 09/03/2008

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,293	LEVINE ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,17,18 and 20-50* is/are pending in the application.

4a) Of the above claim(s) *21-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,17,18,20,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/14/08, 5/23/08, 7/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-13, 17, 18, 20, and 49-50 have been considered but are moot in view of the new ground(s) of rejection.

It is noted to the applicant that the amendment of "the restrictive member being the sole restrictive element" excludes the use of applicant's sleeve (302) shown in figures 13, 14, and 17, as the sleeve also provides a restrictive function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 17, 18, and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girton (US 2002/0183786 A1) in view of VanTassel et al. (US 6,652,555 B1). See figure 6a and respective portions of the specification. Referring to claims 1-7, 9-13, 17, 18, 49, and 50, Girton discloses an implant (600; is *capable* of being placed in a gastrointestinal tract) comprising a substantially planar restrictive member (235), the member being a single unitary sheet membrane and being the sole restrictive member (see fig.6a), further an anchor (ring 230) configured to couple to the stomach (has capability) and to removably couple to the restrictive member (is capable of being removed, by tearing, cutting, etc) and further a plurality of spring clips (625). Girton discloses the restrictive member to be attached to the anchor (P0048), however is silent to mention how the two are specifically attached. VanTassel teaches in the

same field of occlusion devices similar to Girton's, the use of various attachment means (sutures-serving as mechanical members; col.15, lines 1-3; col.18, lines 1-10) to attach a membrane (40) to an anchor (760, 504) as a means for attachment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Girton's anchor with attached membrane (silent of specific attachment means) with VanTassel's teaching of specific attachment means such as sutures, in order to provide a means for attaching the two components. Such attachment means are common in the art. Also, although Girton's device is for occlusion of tissue within the human body, and would seemingly have a size capable of fitting in the stomach, Girton is silent to mention any specific dimensions (7-20 cm is claimed) of the restrictive member and aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) and aperture size of (1-5 cm) since wherein the general conditions of a claim (membrane for use as a partial occlusion device within the body) are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (7-20cm and 1-5cm) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claim 8, Girton discloses an implant having a restrictive member and anchor and discloses various materials for use with the membrane, however does not disclose the specific combination of materials claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the combination of materials claimed, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Such materials are well known in the art of implantable

membranes, see VanTassel as evidence with teaches the use of a permeable fabric combined with a coating of urethane or silicone (col.7, lines 1-18). Such a combination provides the predicable results of impermeability with support.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Girton (US 2002/0183786 A1) in view of VanTassel et al. (US 6,652,555 B1) as applied to claim 1 above and further in view of Seid (US 5,254,133). Girton in view of VanTassel disclose an implant substantially as claimed having a restrictive membrane attached to an anchor by a mechanical element (sutures taught by VanTassel above). Girton in view of VanTassel however disclose the use of sutures instead of hooks. Seid teaches in the same field of medial implantable membranes, the use of hooks and loops as a common mechanical fastener (col.4, lines 1-9), an alternative to sutures (as used by Girton in view of VanTassel). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Girton in view of VanTassel's suture attachment with Seid's teaching of using hook and loop fasteners as an alternative to sutures in order to provide an alternate equivalently known fastener in the art.

Claims 1-4, 10, 11, 12, 13, 17, 18, 20, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (US 5,925,063, cited previously) in view of Stack et al. (US 7,152,607 B2). Khosravi discloses a gastrointestinal implant (fig.4B; col.6, lines 51-55) comprising a substantially planar restrictive member (28+29, is substantially planar since the majority of the member is planar, portion 28), the member being a single sheet membrane (28+29 is one single sheet; although the sheet may have some slits in it, it is still continuous and connected through portion 29 and thus is a single sheet; further, when implanted, all flaps 28

touch and form one single layer membrane) having an interior aperture (33) and an anchor (stent 21) *configured* to couple to the stomach (col.6, lines 51-55) and removably couple to the restrictive member (is considered remov*able*, may tear or cut away), the anchor (stent 21) having an exterior perimeter adapted to contact the stomach (fig.4B), the restrictive member substantially planar with a plane of the anchor (21; the anchor is three dimensional and have many different planes; the restrictive member is planar with one of the planes). Khosravi discloses the implant for placement in the stomach substantially as claimed (col.6, lines 51-55), however does not disclose the size (width) of the restrictive member and of the aperture. Khosravi discloses the implant for placement in the stomach substantially as claimed (any organ, gastrointestinal; col.6, lines 51-57), however does not disclose the size (width) of the restrictive member and of the aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) and aperture size of (1-5 cm) since wherein the general conditions of a claim (membrane for occluding or restricting for use in any organ-which includes the stomach, and for gastrointestinal use) are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges (size of membrane to fit the stomach) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Khosravi discloses a restrictive member (28) coupled to an anchor (21), however uses adhesive (col.4, lines 36-39) instead of a mechanical element such as a hook connection as claimed. Stack teaches in the same field of gastrointestinal implants (abstract) the use of a mechanical attachment element, such as a hook (clips or sutures: as an alternative to adhesives; col.8, lines 25-29) between a restrictive member (pouch) and anchor (ring 73). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

combine Khosravi's gastrointestinal implant having an attachment means (adhesive) with Stack's teaching of an alternate attachment means (sutures or clips) for gastrointestinal implants, in order to provide an alternate attachment means to suit the needs of the patient (this one may be attached at the time of surgery).

Referring to the remaining dependent claims, Khosravi discloses the restrictive member to be made of the materials claimed (col.4, lines 57-60; col.5, lines 1-5). Khosravi discloses the anchor (21) to have a plurality of clips (24, see fig.2, 6C) capable of penetrating tissue (shown to be angled radially outward in fig.6C, thus are capable of penetrating tissue). Khosravi discloses the anchor to be NiTi (col.4, lines 8-12).

Claims 1-13, 17, 18, 20, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. (US 7,152,607 B2) in view of Khosravi (US 5,925,063, cited previously). Stack discloses a gastrointestinal implant substantially as claimed. See figure 10. Stack discloses a restrictive member (pouch; fig.10) comprising a unitary sheet membrane (see figs), the restrictive member being the sole restrictive member, an anchor (ring 62a) configured to couple to the stomach and removably couple to the restrictive member by a mechanical member (col.8, lines 26-29), and spring clips on the anchor (see fig.12; . Stack discloses an implant for placement in the stomach so would seemingly have the dimensioned claimed, however no specific dimensions are mentioned. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) and aperture size claimed (1-5 cm) since wherein the general conditions of a claim (membrane for use as a partial occlusion device within the stomach) are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges (7-20cm and 1-5cm) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Also, although Stack discloses the restrictive member (pouch) to be any of a variety of shapes, such as a short saucer (fig.10; col.4, lines 30-38) that would seem pretty flat, Stack does not specifically disclose a flat shape. Such would be a mere change in the shape of a component. Khosravi teaches in the same field of gastrointestinal devices (col.6, lines 51-57), the use of a flat restrictive membrane (28; see fig.4b) which also provides partial occlusion of fluids. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Stack's restrictive member which is disclosed to have a variety of shapes, with Khosravi's teaching of a flat restrictive member (a specific alternative shape for use in the same field), in order to provide a different shape for occlusion. Both would provide the function of restricting flow therethrough and would be obvious alternatives to one another.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738